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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,389	09/14/2005	Shigeru Kanaoka	05596/HG	2212

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FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER	
PANDE, SUCHIRA	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,389	KANAOKA, SHIGERU	
	Examiner	Art Unit	
	Suchira Pande	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/14/05; 10/24/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Examiner acknowledges election of group I invention claims 1-4 and 6. Restricted application was transferred to the Examiner for examination. Upon review of the case Examiner sees that claim 5 properly belongs to the invention of group I. Hence Examiner is rejoining claim 5 of group II invention with claims 1-4 and 6 of group I invention. Consequently, claims 1-6 are being examined in this action.

2. Claims 7-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions of groups II, III and IV, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5 September 2006.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 19 March 2003. It is noted, however, that applicant has not filed a certified English translation copy of the JAPAN 2003-75552 03/19/2003 application as required by 35 U.S.C. 119(b). Consequently priority of PCT/JP03/11972 application filed on 19 September 2003 is being granted to the claims under consideration.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexander and Raicht (1998) Digestive Diseases and Sciences Vol. 43 No. 12 pp 2652-2658 as evidenced by Ultraspec^{TM}-II RNA isolation system Biotecx Bulletin No. 28, 1993.

Regarding claim 1, Alexander and Raicht teaches a method for preparing a sample to extract RNA (see title where Total RNA purification from Human stool sample is taught) used in a tumor marker detecting method (see abstract where RNA isolated from human stool shown to be useful for detecting human mRNA is taught) for diagnosing colon cancer (See page 2652 par.1-2, where colon neoplasia and methods of diagnosing it are taught) comprising the following process:

a) a process to homogenize the collected biological (human stool) sample in the presence of an RNase inhibitor (Ultraspec II reagent from Biotecx Laboratories contains chaotropic agent 14 M guanidium salt that are potent inhibitors of Rnase), to prepare a suspension thereof (See page 2653 Materials and Methods par. 2-4 under Purification of total RNA from stool samples); characterized by involving no procedure of separating cell components from the biological sample (the method taught by Alexander and Raicht directly homogenizes the stool without separating cell components see page

2653 where frozen piece of stool is made into a slurry and particulates are removed from the suspension by decantation followed by lysis using the Ultraspec II reagent from Biotecx Laboratories).

Thus, claim 1 is anticipated by Alexander and Raicht.

Regarding claim 2, Alexander and Raicht teach wherein the collected biological sample is frozen (see page 2653 par. 2 under Purification of Total RNA from Stool Samples, where freezing for Stool sample in Liquid Nitrogen is taught).

Regarding claim 3, Alexander and Raicht teaches wherein the Rnase inhibitor is guanidine thiocyanate (Alexander and Raicht teach use of Ultraspec II reagent, a single step RNA purification from Biotecx Laboratories. This reagent contains 14 M solution of guanidine salts. The formulation is based on a method of Chomczynski and Sacchi that uses guanidinium thiocyanate-phenol-chloroform for RNA isolation. See Biotecx Bulletin No:28, 1993, Introduction and Reference no 3.).

Regarding claim 4, Alexander and Raicht teach wherein the biological sample is feces (see Title where stool samples ie. feces is taught).

Regarding claim 5, Alexander and Raicht teach a tumor marker detecting method for diagnosing colon cancer, comprising the following processes:

b) a process to extract RNA from the obtained sample for extracting RNA (see page 2653 section titled: Purification of total RNA from stool samples);

c) a process to reverse transcribe the extracted RNA to give cDNA (see page 2654 par. 3-4 where RT-PCR is taught);

d) a process to amplify the obtained cDNA (see page 2654 par. 5-6 where PCR amplification of cDNA is taught); and

e) a process to detect the amplified cDNA (see page 2654 par. 7 and Results par. 3 where detection of amplified cDNA by gel electrophoresis is taught,

in addition to the method according to claim 1 (see above).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander and Raicht (1998) Digestive Diseases and Sciences Vol. 43 No. 12 pp 2652-2658 as evidenced by UltraspecTM-II RNA isolation system Biotecx Bulletin No. 28, 1993 in view of Sano et al. (1995) Cancer Research 55: 3785-3789.

Regarding claim 6, Alexander and Raicht teach method of claim 1 but do not teach wherein the tumor marker is COX-2.

Regarding claim 6, Sano et al. teach wherein the tumor marker is COX-2 (see abstract where COX-2, a colon cancer marker is taught)

It would be prima facie obvious to one of ordinary skill in the art at the time the invention was made to use COX-2 tumor marker taught by Sano et al. in the method of

Alexander and Raicht for diagnosing colon cancer. The motivation to do so is provided by Sano et al.

Sano et al. show enhanced expression of the COX-2 gene in colon cancer tissues. They state " Moreover, the immunoreactive COX-2 was abundant in colonic cancer cells in our study. COX-2 may assume an important role in the activation pathways by which carcinogens can be converted to the reactive intermediates that mutate DNA. These findings suggest that COX-2 induced by stimulation of chemical substances, cytokines, and growth factors may have a role in the initiation, promotion, and maintenance of colorectal cancers" (see page 3788 last 2 paragraphs)

Conclusion

All claims under consideration 1-6 are rejected over prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

JEFFREY FREDMAN
PRIMARY EXAMINER
12/28/07